

REMARKS

This is in response to the 02 October 2009 office action.

Applicant has amended the independent claims (Nos. 23, 30, 36 and 40) to further emphasize the novel features.

Withdrawn claims 1-22 remain canceled without prejudice or disclaimer of the subject matter therein. Claims 35 and 37 also remain withdrawn. Applicant reserves the right to file a continuing application including the subject matter of the canceled claims and the withdrawn claims.

The 35 U.S.C. 102(b) rejection of claims 23-34, 36, 38 and 39.

Claims 23-34, 36, 38 and 39 stand rejected under 35 U.S.C. 102(b) as anticipated by Ellman (U.S. Patent No. 4,428,375).

To support a rejection of a claim under 35 U.S.C. 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference.¹

Claim 23 is directed to a bone instrumentation cover comprising a hollow cap adapted for placement in the body of the animal, for encapsulating a part of the bone instrumentation, for providing a medically safe physical barrier and for separating the bone instrumentation from substantially all of the surrounding soft tissue so that the hollow cap prevents ingrowth of substantially all of the surrounding soft tissue through the cap into the bone instrumentation which projects from the bone. Claim 30 similarly is directed to a bone instrumentation cover comprising a hollow cap shaped to encapsulate a part of a pedicle screw which has been installed in bone in the body of a human, the hollow cap being shaped to encapsulate a part of the pedicle screw which projects from the bone and is in the body of the human, the hollow cap being adapted for placement in the body of the human to separate the part of the pedicle screw in the body of the human from substantially all of the surrounding soft tissue so that the hollow cap prevents ingrowth of bone or tissue through the cap into the bone instrumentation which projects from the bone. Claim 36 is directed to a bone instrumentation cover comprising a cap comprising means adapted for placement in the body of the animal and for separating a

¹ See *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

projecting portion of bone instrumentation which has been installed in bone in vivo in the animal from substantially all of the surrounding soft tissue and for providing a medically safe physical barrier between the part of the bone instrumentation which projects from the bone and the surrounding soft tissue in the animal so that the cap prevents ingrowth of substantially all of the surrounding soft tissue into the bone instrumentation which projects from the bone.

Ellman discloses a bag 15 to compress an organ to assist in healing a fracture in the organ. Ellman discloses "bag 15 has a mesh or network construction" (column 2, line 32). The mesh has openings 19. Ellman states that "another advantage is that the multiple interstices or openings in the net allows ingrowth of tissue through the net openings and around the net solid parts and thus enhances healing." (Column 3, lines 55-58.)

In applicant's claims 23, 30 and 36 the cover or shield is adapted for separating the bone implant from substantially all of the surrounding soft tissue so as to prevent ingrowth. Ellman's bag 15 does not and cannot separate the implant from the soft tissue because the bag 15 has holes in the bag 15 (i.e., a mesh has holes or openings which as disclosed in Ellman permit ingrowth). Accordingly Ellman does not anticipate the claimed invention and Ellman actually teaches away from the claimed invention in that Ellman discloses the desirability of ingrowth (as quoted above) whereas applicant's claimed invention prevents ingrowth. One following the teaching of Ellman would be discouraged from following the path set out by applicant and would be led in a direction away from the invention provided by the applicant.

Ellman discloses that the mesh or network of the bag 15 has holes 19 which are "3-9 mm in size" (column 2, lines 46-52). Even a layman would know that Ellman's bag 15 with holes that size does not and can not prevent "ingrowth of substantially all of the surrounding soft tissue through the cap into the bone instrumentation which projects from the bone" as recited in claim 23, is not "adapted to separate the part of the pedicle screw in the body of the human from surrounding bone and soft tissue..." as recited in claim 30 and is not a means "for separating a projecting portion of bone instrumentation which has been installed in bone in vivo in the animal from substantially all of the surrounding soft tissue and for providing a medically safe physical barrier between the part of the bone instrumentation which projects from the bone and the surrounding soft tissue in the animal so that the cap prevents ingrowth of substantially all of the surrounding soft tissue into the bone instrumentation which projects from the bone" as recited in claim 36.

A declaration under 37 CFR 1.132 accompanies this amendment. The declaration is by Jeffery Thramann (Chairman of the board of Lanx, Inc., a licensee of subject matter in the present application) and states that “Ellman’s device would not ‘provide a medically safe physical barrier between the part of the bone instrumentation and the surrounding bone and soft tissue...’ nor would it ‘prevent ingrowth of substantially all of the surrounding soft tissue through the cap into the bone instrumentation’....” The declaration by Jeffery Thramann provides evidence that Ellman does not teach or suggest the claimed subject matter.

For at least the above-noted reasons, Ellman does not anticipate the invention of independent claims 23, 30 and 36 (and dependent claims 24-29, 31-34, 38 and 39). Accordingly, applicant requests reconsideration and withdrawal of this ground of rejection.

The 35 U.S.C. 102(b) rejection of claims 40-42.

Claims 40-42 stand rejected under 35 U.S.C. 102(b) as anticipated by Coombs et al. (U.S. Patent No. 4,564,007).

Claim 40 is directed to the combination of a bone implant and a barrier comprising a bone implant capable of extending from the bone of an animal and a barrier material adapted for snugly covering only the portion of the bone implant in the animal which projects from the bone and separating the bone implant from substantially all of the surrounding soft tissue, wherein the barrier material is a medically safe physical barrier between the portion of the part of the bone implant that is covered and the surrounding soft tissue of the animal and wherein the barrier material prevents ingrowth of substantially all of the surrounding tissue into the instrumentation.

As stated in the Thramann declaration Coombs is directed to an orthopaedic external fixation device for connecting bone pins to the fragments of a fractured bone to form a support holding the bone fragments in a desired positional relationship while the fracture re-unites. The declaration by Jeffery Thramann provides evidence that Coombs does not teach or suggest the claimed subject matter. Coombs device is for “external” fixation (see column 1, line 4 and line 48) device and in the portion of Coombs describing how the device is used (see especially column 4, lines 6-28) it is evident Coombs’ device would not prevent ingrowth of soft tissue with respect to the implant.

Claim 40 requires a barrier material adapted for snugly covering only the portion of the bone implant in the animal which projects from the bone and separating the bone implant from substantially all of the surrounding soft tissue. The Coombs external device is not adapted or

snugly covering the portion of the bone implant and is not adapted for separating the bone implant from substantially all of the surrounding soft tissue. Coombs is designed to grasp and hold the end of the pins and is not designed to separate the soft tissue from the pin (implant) portion extending from the bone to through soft tissue to the external of the body.

For at least these reasons applicant requests reconsideration and withdrawal of this ground of rejection.

The 35 U.S.C. 103(a) rejection of claims 43-44.

Claims 43-44 stand rejected under 35 U.S.C. 102(b) as obvious over Coombs et al. in view of Ellman.

Claims 43 and 44 are dependent claims and add that the barrier material is hydrogel.

The office action urges "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the devices of Ellman and Coombs having a hydrogel material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice." In Coombs the spacer member (Fig. 3) is of one-piece plastics material construction (col. 3, lines 7-8); the stabiliser member (Fig. 4) is of one-piece plastics material construction (col. 3, lines 12-13); and the capping member (Fig. 7) is of one-piece plastics material construction (col. 3, lines 43-44). The one-piece plastics material construction is provided to ensure adequate structural support for the pins. The office action does not explain why one of ordinary skill would want to use hydrogel in place of the plastics material of Coombs. The use of hydrogel would not have been obvious for various reasons such as that it would not be necessary as plastics are suitable for Coombs device and at least some hydrogels would not provide adequate structural support for pins.

For at least these reasons applicant requests reconsideration and withdrawal of this ground of rejection.

Conclusion.

For all of the above reasons claims 23-34, 36 and 38-44 appear to be in condition for allowance and such is respectfully requested.

If there is any issue remaining to be resolved, the examiner is invited to telephone the undersigned so that resolution can be promptly effected.

It is requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response with the fee for such extensions and shortages in other fees, being charged, or any overpayment in fees being credited, to the Account of Barnes & Thornburg, Deposit Account No. 02-1010 (6714-46501).

Respectfully submitted,

BARNES & THORNBURG LLP

A handwritten signature in dark ink, appearing to read "Richard B. Lazarus". The signature is fluid and cursive, with the first name "Richard" being more prominent.

Richard B. Lazarus

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